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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,325	02/17/2004	Steven C. Quay	02-04CIP3	1085

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,325	QUAY ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2,3,8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7 and 10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of Group I, claims 1, 4-7 and 10-16, in the reply filed on May 9, 2006 is acknowledged. Claims 2, 3, 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 12 and 13 have been amended. No claims have been canceled. Claims 17-20 have been added. Accordingly, claims 1, 4-7 and 10-20 are examined on the merits herewith.

In their traversal, Applicants assert that all the claims should be examined together, because the claims of Group II are dependent claims that include the limitations of the claims of Group I because they depend from the claims of Group I. No additional searching is required. The claims of Group II do not have a separate utility, and the composition must be administered by an aerosol spray. In reply, the claims of Group II are not proper dependent claims. They have a different preamble from claim 1 and are consequently drawn to a different invention. Claims 2 and 8 are drawn to Y2 receptor binding compounds, while claim 1 is drawn to a composition comprising an aqueous solution of a Y2 receptor binding compound and an actuator. Claim 1 is equivalent to a kit claim, wherein the kit comprises a pharmaceutical device. Claims 3 and 9 are drawn to aqueous solutions, but were included in Group II because they may easily be amended for presentation as proper dependent claims in this group. Had claim 2, for example, been written as a proper dependent claim, it would have recited the pharmaceutical composition of claim 1, wherein the Y2 receptor binding compound is or comprises PYY(3-36). The search for Group II in the original claim set does not entirely overlap with that for the original claims of Group I, because searches for PYY and PYY(3-36) would

have been required, and the claims of Group II require a separate examination. In view of the foregoing, the restriction requirement is maintained and is made final.

Drawings

The drawings are objected to because the penultimate page of the drawings, p. 15 of 16, is blank. This page is labeled "Figure 21," but no figure appears on this page. This page should be deleted. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer (on-line catalogue for Ing. Erich Pfeiffer GmbH, Pharma Division, Nasal Application Systems, www.pfeiffer.de, printed from the Internet on May 18, 2006) in view of Cowley et al. (US 2005/0176630), Pang et al. (US 2004/0228846), Grandt et al. ("Novel generation of hormone receptor specificity by amino terminal processing of peptide YY," Biochem Biophys Res Comm 186(3):1299-1306, 1992), Batterham et al. ("Gut hormone PYY(3-36) physiologically inhibits food intake," Nature 418:650-654, 2002), and Jones (US 6,5996,740). Pfeiffer discloses that a wide range of intranasal drug delivery devices have been available for decades, and the on-line catalogue shows some of these devices (see enclosed pages). Pfeiffer does not list their product with catalogue numbers. On pages 90, 154 and 155 of the specification, Applicants disclose that they purchased an intranasal drug delivery device (nasal spray pump with safety clip, product no. SAP # 60548) from the American division of Pfeiffer GmbH in Princeton, NJ. This device delivers 0.1 ml doses with droplets of a particular size range that Applicants measured. This device produces an elliptical spray of a particular size and shape that Applicants measured. These features are properties of a commercially available device and are not inventive work on the part of Applicants. It is prima facie obvious to put a

therapeutic agent into a commercially available device designed to dispense therapeutic agents. This combination is an obvious composition. Applicants do not disclose that such a spray size or shape or such droplet sizes are associated with any particular result or effect or any particular improvement over the prior art. For example, Jones discloses that conventional Venturi-type atomizers or metered dose spray devices for intranasal drug delivery produce droplets of 100-200 microns, and greater than 98% of the droplets are larger than 16 microns (see col. 5, lines 62, to col. 6, line 3).

On p. 154 of the specification, lines 5-6, Applicants note their surprising result that PYY(3-36) can be aerosolized and still be therapeutically effective. But, Cowley et al. disclose compositions and methods for treating obesity, or decreasing calorie or food intake (which induces weight loss) in humans comprising administering a therapeutically effective amount of a PYY peptide (a Y2 receptor-binding peptide), such as PYY(3-36), that is formulated as an aerosol for inhalation (see paragraphs 3, 5, 8-13, 137 and 138) and intranasal administration (see claims 1 and 5). PYY(3-36) is the preferred PYY (see paragraphs 86 and 91). An effective dose of a PYY peptide is 1 μg to about 5 mg (see paragraphs 140-141). An effective doses produces serum levels of 40-50 pM (see paragraph 143), while the normal circulating level of PYY(3-36) is about 8 pmol/L (pM) (see paragraph 144). Because Cowley et al. disclose that PYY(3-36) may be administered as an aerosol as a therapeutically effective route of administration, Applicants' result is not unexpected and is not surprising. Similarly, Pang et al. disclose a composition and method for treating obesity in humans comprising administering intranasally a PYY peptide (see paragraphs 18, 19, 155 and 182). The composition may be a powder, spray or aerosol (see paragraphs 168-170). Thus, Applicants' result is not surprising in view of Pang et al. Although Pang et al. do not specifically disclose that PYY(3-36) is a therapeutic agent, Batterham et al. disclose that this peptide decreases appetite and food intake

in humans (see p. 652, right col.). Thus, this peptide may be used to treat obesity or induce weight loss. Grandt et al. disclose that PYY(3-36) may be used therapeutically to increase blood pressure or decrease pancreatic secretion (e.g., insulin secretion) (see p. 1304, Discussion).

In view of the foregoing, a holding of obviousness is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays o.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-05-19

Rosanne Kosson

ROBERT A. WAX
PRIMARY EXAMINER